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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,480

11/20/2003

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US-102

9006

38108 7590 06/16/2008

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EXAMINER

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ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

06/16/2008

PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YOSHIYA GUNJI and HISAHY YASUEDA

Appeal 2008-2540
Application 10/716,480
Technology Center 1600

Decided: June 16, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 2-4, 6 and 7. The only remaining claims, claims 8 and 9 were withdrawn from consideration (App. Br. 4). We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to an isolated DNA encoding a mutant LysE protein. Claim 2 is illustrative:

2. An isolated DNA encoding a mutant LysE protein, wherein said mutant is selected from the group consisting of:

A) a protein comprising the amino acid sequence of SEQ ID NO: 2 except that the glycine residue at position 56 is replaced with another amino acid residue, and

B) a protein comprising the amino acid sequence of SEQ ID NO: 2 except that

i) the glycine residue at position 56 of SEQ ID NO: 2 is replaced with another amino acid residue, and

ii) not more than 10 amino acid residues at positions other than the 56th residue are substituted, deleted, or inserted, wherein said mutant imparts resistance to S-(2-aminoethyl) cysteine when introduced into a methylotroph.

The Examiner does not rely on evidence to support the rejections of record.

The rejection as presented by the Examiner is as follows:

1. Claims 2-4, 6, and 7 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

DISCUSSION

Claim Interpretation:

Claim 2 is drawn to an isolated DNA encoding a mutant LysE protein. Claim 2 defines the mutant LysE protein as being either:

A) a protein comprising the amino acid sequence of SEQ ID NO: 2 except that the glycine residue at position 56 is replaced with another amino acid residue, and

B) a protein comprising the amino acid sequence of SEQ ID NO: 2 except that

i) the glycine residue at position 56 of SEQ ID NO: 2 is replaced with another amino acid residue,

ii) not more than 10 amino acid residues at positions other than the 56th residue are substituted, deleted, or inserted,

wherein said mutant imparts resistance to S-(2-aminoethyl) cysteine when introduced into a methylotroph.

Findings of Fact:

1. Appellants' Specification discloses that "[o]ne embodiment of the DNA of the present invention is a DNA encoding for a protein which has the amino acid sequence of SEQ ID NO: 2, whereby at least the glycine residue at position 56 is replaced with another amino acid residue" (Spec. 7: ¶ 0032).

2. Appellants' Specification discloses that a more specific embodiment of the DNA of the present invention is a DNA encoding for a protein which has the amino acid sequence of SEQ ID NO: 2 and includes a mutation for any of the following:

- (i) replacement of the glycine residue at position 56 in SEQ ID NO: 2 with another amino acid residue;
- (ii) replacement of the glycine residue at position 56 in SEQ ID NO: 2 with another amino acid residue, and replacement of the alanine residue at position 55 in SEQ ID NO: 2 with another amino acid residue;
- (iii) replacement of the glycine residue at position 56 in SEQ ID NO: 2 with another amino acid residue, and replacement of the aspartic acid residue at position 137 in SEQ ID NO: 2 with another amino acid residue.

(Spec. 7: ¶ 0033 – 8: ¶ 0036).

3. Appellants' Specification discloses that

[t]he DNA of the present invention may encode an amino acid sequence including substitution, deletion, insertion or addition of one or several amino acid residues at positions other than the 55th, 56th and 137th positions so long as the encoded mutant LysE has any of the aforementioned mutations and exhibits the function of the LysE protein in a methanol-assimilating bacterium.

(Spec. 9: ¶0041).

4. Appellants' Specification discloses that

[a] DNA encoding for a protein substantially identical to the aforementioned mutant LysE can be obtained by modifying the nucleotide sequence of the mutant *lysE*. For example, site-directed mutagenesis can be employed so that substitution, deletion, insertion or addition of an amino acid residue or residues occurs at a specific site. Furthermore, a DNA modified as described above can also be obtained by conventionally-known mutation treatments. Examples of such mutation treatments include a method of treating the DNA before the mutation treatment *in vitro* with hydroxylamine or the like, a method of treating a microorganism, for example, an *Escherichia* bacterium, containing DNA before the mutation treatment with ultraviolet ray irradiation or a mutagenesis agent

used in a usual mutation treatment such as N-methyl-N'-nitro-N-nitrosoguanidine (NTG) or nitrous acid, and so forth.

(Spec. 9: ¶ 0042).

5. Appellants' Specification exemplifies the screening of a functional type *LysE* from a library of artificially mutated *lysE* (*see e.g.*, Spec. 28: ¶ 103 - 29: ¶ 105).

Analysis:

Claims 3-4, 6 and 7 depend from or require the DNA of claim 2. Accordingly, we focus our attention on claim 2.

The Examiner does not dispute that Appellants' have fully enabled a DNA that encodes a mutant LysE protein comprising the amino acid sequence of SEQ ID NO: 2 except that the glycine residue at position 56 is replaced with another amino acid residue (Ans. 3). Thus, the Examiner finds that Appellants' Specification provides an enabling description of an isolated DNA within the scope of claim 2, part A.

The Examiner's concern is whether it would require undue experimentation for a person of ordinary skill in the art to make and use a DNA encoding a mutant LysE protein, wherein the mutant comprises (i) the replacement of the glycine residue at position 56 of SEQ ID NO: 2 with another amino acid residue, *and wherein (ii) not more than 10 amino acid residues at positions other than the 56th residue are substituted, deleted, or inserted* (Ans. 7).

In this regard, the Examiner finds that there is

[n]o description in the specification or the art [that] provides particular residues whose encoding is important within the disclosed sequence so that its mutant LysE-nature is maintained

except for amino acid residue glycine 56. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members.

(*id.* at 5).

The Examiner does not, however, provide an evidentiary basis to explain why it would require undue experimentation for a person of ordinary skill in the art to make and test DNA's within the scope of the claimed invention following the methodology set forth in Appellants' Specification or otherwise known to those in this art at the time the invention was made (*see e.g.*, FF 1-5).

The starting material for the DNA set forth in claim 2 is a DNA that encodes a protein of SEQ ID NO: 2. An amino acid sequence supports "the entire genus of DNA sequences" that can encode the amino acid sequence because "the state of the art has developed" such that it is a routine matter to convert one to the other. *In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004).

The Examiner recognizes that Appellants' Specification "describes and enables means for identifying other mutant LysE encoding genes using *in vitro* mutation, introduction of the DNA into *Methylophilus methylotrophus*, and selection on S-(2-aminoethyl)cysteine containing media" (Ans. 5). In this regard, we note that Appellants' Specification discloses that "site-directed mutagenesis can be employed so that substitution, deletion, insertion or addition of an amino acid residue or residues occurs at a specific site" (FF 4). "It is undisputed that by 1988 those skilled in the art knew several techniques for altering genetic

sequences, including deletion and point mutations.” *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005).

Appellants’ Specification also exemplifies screening methodology that may be used to identify those mutations that exhibit the ability to impart resistance to S-(2-aminoethyl) cysteine when introduced into a methylotroph (FF 5). “Enablement is not precluded by the necessity for some experimentation such as routine screening.” *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

In sum, the Examiner failed to provide an evidentiary basis to support a conclusion that it would require undue experimentation to make and screen any or all mutations within the scope of the claimed invention. The mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be “undue” in this art. The Examiner has also failed to provide an evidentiary basis to support a conclusion that once made, a person of ordinary skill in the art would not be able to use a DNA encoding a mutant LysE protein within the scope of Appellants’ claimed invention. Here, as in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986), there is not a shred of evidence that undue experimentation will be required by those skilled in the art to practice Appellants’ claimed invention.

We are also not persuaded by the Examiner’s assertion that “the substitutions contemplated within SEQ ID NO:2 can result in an unstable product, rendering the invention unpredictable” (Ans. 8). There is no evidence on this record to support a conclusion that the number of inoperative embodiments within the scope of Appellants’ claimed invention

are excessive. As set forth in *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. “It is not a function of the claims to specifically exclude ... possible inoperative substances. . . .” *In re Dinh-Nguyen*, 492 F.2d 856, 859-59 . . . (CCPA 1974) (emphasis omitted). *Accord, In re Geerdes*, 491 F.2d 1260, 1265 . . . (CCPA 1974); *In re Anderson*, 471 F.2d 1237, 1242 . . . (CCPA 1973). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. *See, e.g., In re Cook*, 439 F.2d 730, 735 . . . (CCPA 1971).

On reflection, we find that the Examiner failed to meet her initial burden of providing the evidence necessary to establish a prima facie case of lack of enablement. *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971). Accordingly, we reverse the rejection of claims 2-4, 6, and 7 under the enablement provision of 35 U.S.C. § 112, first paragraph.

CONCLUSION

In summary, we reverse the rejection of record.

REVERSED

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